The Ethics of Adolescent Inclusion in HIV Research in sub-Saharan Africa

An analysis of adolescents capacity to participate in biomedical research

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Abstract

Background: Adolescents and young adults between the ages of 10 to 24 represent 37% of people living with HIV in sub-Saharan Africa. Despite their increased vulnerability, the adolescent population is often excluded from biomedical and behavioral research. While the importance of involving adolescents in health research is widely recognized, their participation is often complicated by ethical, legal, and practical issues. One critical but understudied area in research ethics is the cognitive capacity of adolescents of different ages to understand and provide informed consent. This paper explores adolescents' cognitive capacity to understand and provide informed consent using a modified version of the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) in Rakai, Uganda. MacCAT tool is a modified semi-structured interview that assists investigators in assessments of patients' competence to consent to research.

Method: The study used qualitative descriptive analysis drawn from data collected in Rakai, Uganda. Data sources included semi-structured in-depth interviews using the MacCAT-CR with selected study participants (N =14); including adolescents (n=7), and their parents/guardians (n=7).

Results: The findings suggest that adolescents' level of knowledge and understanding of informed consent did not differ from that of parents/guardians level of understanding. Adolescents also displayed independent decision-making abilities and a high level of competency indicating their ability to self-consent in research. Taking this perspective will contribute to shaping future research and policy guidelines regarding adolescents' participation in research in sub-Saharan Africa. More research are needed to further understand and explore methods for ethically involving adolescents in research, especially research related to sexual health and research in low and middle income countries.

Background

The global HIV and AIDS response over the past decade has resulted in a significant decline of HIV incidence and AIDS-related deaths between 2010-2018 (UNAIDS, 2018). Despite these gains, the burden of HIV and AIDS continues to rise in certain regions and among vulnerable key populations. Approximately 6,000 new infections occur every day, and about two-thirds of the global daily infections occur in sub-Saharan Africa (WHO, 2020). Adolescents and young adults between the ages of 10 to 24 represent 10% of new infections globally and about 1.5 million (88%) live in sub-Saharan Africa (UNICEF, 2020).

Improved access to antiretroviral therapy (ART) in sub-Saharan Africa in the past decade resulted in an increased number of children (infected with HIV at birth) surviving to adolescence. Coupled with sustained high HIV incidence, nearly 1.5 million adolescents, between the ages of 10 and 19, in sub-Saharan Africa are currently living with HIV (UNICEF, 2020). Adolescent girls and young women are particularly the most vulnerable group to becoming infected with HIV, and they remain the most affected ones today compared to adolescent boys (WHO, 2020). Of all new HIV infections occurring in sub-Saharan Africa in 2018, 80% are among adolescent girls aged 15-19 years (UNAIDS, 2019).

A body of evidence has identified biological, behavioral, and structural factors that increase the vulnerability of adolescent girls' to acquiring HIV and AIDS. Some of these factors include socioeconomic status, family structure, school enrollment, and place of residence (Govender et al., 2019; Mabaso et al., 2018; Marshall et al., 2009; Pettifor et al., 2016). The unequal cultural and socioeconomic status of men and women in many societies is another main driver contributing to the disparity of gendered health outcomes. Societal norms supportive of male superiority, economic control, and sexual entitlement leads to unequal power dynamics among men and women (Niëns & Lowery, 2009). These factors limit adolescent girls' and

women's ability to negotiate safer sex, and leaves them vulnerable to unsafe sexual behaviors, increasing their chances of acquiring sexually transmitted diseases including, HIV and AIDS (Mabaso et al., 2018). Most adolescent girls and young women in sub-Saharan Africa encounter overlapping negative social and structural factors that increase their risk of HIV and AIDS when compared to adolescent boys (Mabaso et al., 2018).

It is critical to understand the social processes that influence young people's vulnerability to HIV and other sexually transmitted infections, such as their age of sexual debut, number of sexual partners, and risky sexual practices. It is also important to study the extent to which current cultural norms, social structures, and policies shape adolescent's sexual health. For example, in Ethiopia, despite the national policy that prohibits marriage under the age of 18, child marriage, especially of girls, is highly prevalent in the northern regions. The practice of early marriage in the Amhara region is seen as a way to ensure sexual purity of young girls and uphold family honor by the society (UNICEF, 2016). In contrast, a qualitative study done in the same region reported 81% of child brides describing their marriage and their sexual initiation as unwanted and forced (Care, 2014). Early marriage is also associated with increased risk of acquiring HIV and AIDS for young women due to increased coital frequency and decreased ability to negotiate safer sex with an infected partner (Clark, 2004).

Participation of Adolescents in Research

Despite abundant evidence of adolescent's vulnerability to becoming infected with HIV and AIDS, the adolescent population is often excluded from biomedical and behavioral research (Santelli, Haerizadeh, & McGovern, 2017). Globally researchers acknowledge the need for adolescents' involvement in biomedical and behavioral research for the development of evidence-based intervention. Over the past decade, international research guidance has shifted

towards the proactive inclusion of adolescents in health research. However, much evidence and debate on this topic has focused on high-income settings, and involvement of adolescents in health research has been limited, and is complicated by ethical, legal, and practical issues in most low income resources settings, including countries in sub-Saharan Africa (Cheah & Parker, 2014; Marsh et al., 2019).

To best understand the issues and challenges regarding adolescents' participation in research, it is best to first explore who is considered an adolescent and how legal definitions and national policies influence practices. The World Health Organization (WHO) defines adolescents as those aged 10-19 years and youth as those aged 15-24 years (WHO*,* 2020). However, these demarcations of the age range and who is considered a minor are contextual and dependent on the physical, cognitive, and social development of the individual (Fox et al., 2013). In most countries, including in sub-Saharan Africa, eighteen is the age of majority (a threshold of adulthood when minors take legal control over their own actions, as declared by law). However, a few countries, such as Iran, Indonesia, or the United Kingdom allow adolescents in a specific age group to attain "majority" earlier at the age of 14 or 16 in all issues including health care and research participation (Fox et al., 2013; OECD Family Database , 2016; Sexual Rights Database, 2016).

A universally agreed-upon standard within the Convention on the Rights of the Child - a legal framework adopted by the United Nations which sets out the civil, political, economic, social, health and cultural rights of children - states that every human being under the age of 18 is considered a child, unless age of majority is attained by national law (OHCHR | Article 1, 1989). Nonetheless, adolescents in some countries are sometimes engaged or forced to engage in adult activities such as early marriage, childbearing, and labor at a young age without officially

attaining age of majority under national law. In Northern Sudan, for example, there is no minimum age of marriage laws, and girls can be married off as young as 10 years old (UNFPA/Sudan, 2018). Girls in Tanzania can also be married off at the age of 12 unless the marriage is not consummated until the girl reaches the age of 15 (Sanstrom & Theodorou, 2016). While some settings, like the ones mentioned above, allow even early adolescents to engage in adult activities such as marriage, they are often prohibited from directly participating in research without parental involvement.

However, over in recent decades, the international research guidance has shifted towards the proactive inclusion of adolescents in health research. With the purpose of protecting a minor's welfare and rights, the inclusion of adolescents in research must adhere to ethical guidelines. This inclusion process usually requires parental consent (parent/guardian approval) and child assent (affirmative agreement/ approval of the minor to participate, assuming parental consent is granted) (Al-Sheyab et al., 2019). These rules are set within the international guidelines of ethical conduct in research in humans such as the Belmont Report, the Helsinki Declaration and its amendments, and the International Ethical Guidelines for Health-related Research Involving Humans (The Belmont Report, 2010; The World Medical Association Declaration of Helsinki, 1964; World Health Organization & Council for International Organizations of Medical Sciences, 2017).

Consent is defined as "voluntary agreement to or acquiescence in what another proposes or desires; compliance, concurrence, permission" (Oxford English Dictionary, 1989). Consent can be expressed either verbally or in writing. In cases of research or health interventions, *informed consent* must be obtained. Informed consent is defined as the subject participating in the research or medical procedure should receive information about the activity, and must clearly

indicate an understanding of the risk and benefits of participation (Shah et al., 2018). Participants should also voluntarily confirm willingness to participate in the intervention/research, and the process of obtaining informed consent should not be coerced (Fox et al., 2013).

However, obtaining parental consent can sometimes pose challenges when conducting sexual and reproductive health research with adolescents. The evidence suggests that adolescents are more likely to disclose sensitive information about their sexual health and seek care without the involvement of their parents or guardians (Santos, 2012). While some exceptions to waive parental consent exist under certain circumstances, according to the revised guidelines "*Ethical consideration in planning and reviewing research studies on sexual and reproductive health in adolescent,*- set by the WHO, adolescents who have not reached the legal age in their national jurisdiction do not have the legal right to consent to research autonomously (WHO, 2018).

The WHO guidance is based on the theory that those who are under the age of majority do not have the cognitive capacity to comprehend elements of informed consent (understanding of study procedure and risk/ benefit of participation); therefore, they are unable to consent to participate in research. However, research on the cognitive ability of adolescents suggests that their decision-making capacity emerges as early as 12 years of age (Hein et al., 2015a). For many decades, the debate about a minor's competence to give informed consent, competence to assent, and make autonomous medical decisions has relied on their presumed decision-making capacity (Hein et al., 2015b). If adolescents have the ability to understand elements of informed consent and capable of making independent decision, they can be considered to participate in research. In return, expanding the knowledge to be gained about their lives and their vulnerability.

Theoretical Framework

Research ethics, particularly for studies conducted with minors, is perceived as a balancing act between protection from research harm and inclusion in research to bring about social benefits. The "Child Cognitive Development Theory" by Jean Piaget (1936), helps to explain this concept. Piaget describes child intellectual development as a process which occurs due to biological maturation and interaction with the environment which subsequently influences their social awareness and moral maturity (Huitt, & Hummel, 2003). Piaget further divided child cognitive development into four stages and argued that by stage three (concert operational stage), children aged 7-11 years begin to gain the ability to think logically and connect concepts that allow them to deal with their immediate environment.

By Stage four (formal operational stage), children aged 12 years and older start to think abstractly and reason about hypothetical problems. They also begin to think more about moral, philosophical, ethical, social, and political issues that require theoretical and abstract reasoning (Huitt, & Hummel, 2003). While Piaget's theory suggests each child goes through these four stages and intelligence level at each stage is different from the other stages, children's intellectual development is also not just a quantitative process. The theory emphasizes there is a qualitative change in how children think as they advance through these four stages.

By building on cognitive development theory, adolescents, who are at a developmental stage between childhood and adulthood, are categorized in the formal operational stage of the intellectual developmental theory (See appendix 1for a visual framework of the four stages). This population group often can reason through complex ideas and have high levels of autonomy. They develop logical and deductive capabilities, and they are able to conduct hypothetical analysis (Parsapoor et al., 2014). Nevertheless, in some cases such as research participation, they cannot make their own choices.

The theoretical question this paper will explore is whether or not adolescents are capable of making independent decisions about participating in research using the MacArthur Competence Assessment Tool (MacCAT) tool. The MacCAT tool is one of the standard international tools for the assessment and evaluation of competences of consent in different clinical settings. The measure was originally designed for adult populations. But a number of studies, primarily in developed countries, later adopted and tested the tool to be used on the adolescent populations, which measured competence to consent to clinical research and medical interventions (Grisso et al., 1997; Hein et al., 2014; Viljoen et al., 2009). Additionally, studies conducted in Iran, China and Spain, evaluating the cross-cultural adaptation of the MacCAT tool, indicated that the tool is not culture-specific and that it can be translated to any language to suit different societies. (Baón-Pérez et al., 2017; Lan et al., 2013; Saber et al., 2016). These findings suggest that the toolis adaptable and applicable to different contexts including low and middle income countries.

Contextual Background

Uganda is one of the countries with the youngest populations in the world; about 56% of its population is under the age of 18. While the country has a long history of successful HIV prevention, the burden of HIV and AIDS among some key populations (men who have sex with men, sex workers, adolescent girls and young women) is still an issue. UNAIDS estimated that in 2018, about 1.4 million people were living with HIV. Adolescents, especially girls, are at increased risk for becoming infected with HIV infection (UNAIDS, 2018). According to the Uganda AIDS Commission, 26% of new infections are among 15-24 year old's and HIV prevalence is almost four times higher among girls than boys of the same age group (Uganda AIDS Commission, 2018).

The National Guidelines for Research involving Humans as Research Participants (NGHRP) of Uganda defines minors as those below the age of 18. Parental consent is generally required for minors to participate in research unless the child is an emancipated minor (individuals below the age of 18 years who are pregnant, married, have a child, or are self-sufficient) or considered mature minors (14-17 years of age who have drug or alcohol dependency or a sexually transmitted infection) (Clinical Research Regulation For Uganda, 2020).

In Uganda, assessment tools such as the Enhancing Assessment of Common Therapeutic factors (ENACT) and The Pediatric Evaluation of Disability Inventory (PEDI) have been previously used to evaluate research participant competency to participate in health research (Kakooza et al., 2018; Kohrt et al., 2015), but no previous study used MacCAT tool to assess cognitive capacity on adult or adolescent population. The adaptation of the MacCAT tool for this study was in accordance with the content of the research project, i.e. the Rakai Community Cohort Study (RCCS) in Rakai, in Southcentral Uganda. Given the purpose of this study is to assess understanding of elements of informed consent, the version used of the MacCAT-CR was adopted according to information about study procedure, risk and benefits, and voluntariness. It includes a summary of the consent information (disclosure) followed by questions that examine participant understanding of the content. The interview guide was then translated in Luganda language to accommodate Luganda-only speaking study participants.

Aim of the Study

Accurate assessment of adolescent's decision-making capacity about research participation is essential for making informed judgment about whether to include capable adolescents to participate in research, while protecting those who lack the capacity to make

decisions by themselves. This research report will describe the findings from a qualitative study that explored the cognitive capacity of adolescents in understanding different elements of informed consent risk (risks about potentially participating in the study), benefit (personal and community benefits to be gained from participating in the study), and voluntariness (ability to withdraw from the study). The study aims to compare adolescents' understanding of elements of informed consent with that of parents/guardians' understanding. If adults and adolescents in this study do not differ in their capacity and reasoning, then adolescents should have the right to consent and participate in research. The learning from this study will contribute to shaping future research and policy guidelines regarding adolescent's participation in research.

METHODS

Research Design

This exploratory qualitative study was a nested study based within the Rakai Community Cohort Study (RCCS). RCCS is an open population-based cohort which enrolls all consenting adults and adolescent residents aged 15-49 in approximately 50 communities distributed throughout the Rakai district in Uganda conducted by the Rakai Health Science Program (RHSP; a collaborative Biomedical Research and Service delivery organization). The RCCS household census also includes early adolescents (10-14 years) although they are not typically included in the RCCS study (Rakai Community Cohort Study - RCCS, 2021).

General data collection in RCCS include, detailed sociodemographic information, behavioral and sexual network data, mobility, health and service utilization, and blood sample for HIV testing. Participants who are enrolled in RCCS are linked to free service delivery programs such as HIV testing, HIV care and treatment, voluntary medical male circumcision and other health promotion programs.

In collaboration with RHSP, *The Structural and Social Transitions among Adolescents and Young Adults in Rakai* (SSTAR) project aims to investigate the influence of social structural determinants on transitions from adolescence to adulthood. The SSTAR Bioethics Project is a supplement to SSTAR, with the aim of understanding the ethics of conducting research with adolescents and how a variety of factors contribute to adolescents being excluded from health research. This exploratory qualitative analysis is developed from data drawn from a nested mixed-method bioethics project.

Data Collection

For the Bioethics study, adolescents and parents were recruited from households participating in the larger RCCS cohort study. 80 dyads with 160 total participants (80 adolescents and 80 parents/guardians) were recruited and included in the study . Adolescent participants were further segmented by gender and life stage, including early adolescence (10-14 years old) (n=40), mid-adolescence (15-17 years old) (n=20), and late adolescence (18 and 19 years old) (n=20). All adolescents were recruited from RCCS household. Parents or guardians were selected based on whether they are parents or guardians of the recruited adolescent. Data collection for this study is not complete and currently on-going. Due to limited data that are available at a present day (n=14), this paper will only focus on early (10-14 years old) (n=3), mid adolescents (15-17 years old) (n=4), and their parents/guardians (n=7 adults). This research will only provide preliminary findings.

MacCAT-CT Interviews

Semi-structured interviews were conducted using the MacCAT-CT tool and it includes an exploratory investigation of the cognitive capacity of adolescents and parents to provide informed consent. The interview was administered in-person, in a private room, by experienced

adult RHSP interviewers who are trained in conducting these interviews and to work with adolescent population. The interview took place right after informed consent, assent, and/or parental permission was obtained at the two of RCCS hubs, Lusaka and Manama. Each interview took one hour on average and all interviews were recorded and transcribed. Interviews conducted in Luganda language was translated back to English language for analysis.

Measurement tool

The MacCAT-CR is a semi-structured interview which relies on international criteria to assess competence in understanding informed consent for adult populations (Dunn et al., 2006; Koelch et al., 2010). Its use on children and adolescent population has been tested showing high levels of validity and reliability. A 2014 study tested the accuracy of MacCAT-CR tool on adolescents and compared it with the reference standard tool for adults and found that, overall accuracy of the MacCAT-CR total score in classifying competence as 0.78, confirming the accuracy of the instrument (Hein et al., 2014).

The tool is a multi-item scale consisting 17 items; it is used to disclose relevant information to study participants about the research purpose and procedure, risk and benefits of participating, as well as voluntariness and choice to participate in research. Participants are encouraged to explain the contents they have understood after each disclosure and examined the understanding of information and reasoning of subjects. Evaluation of subjects reasoning has several parts and it is assessed in four areas of competence to consent. These include: 1) Understanding of disclosed information about the nature of the research project its procedures, and associated risks and benefits of participation; 2) Appreciation of the effects of research participation (or failure to participate) on subjects' own situations; 3) Reasoning in the process of deciding about participation and focusing on participant's abilities to compare and contrast in

light of risks and benefits; and 4) Expressing a choice about research participation (Schaefer, 2011). To achieve the aim of this preliminary data research report (comparing adolescents' knowledge and understanding of the risks, benefits, and voluntary participation in research with parents/guardians understanding), the paper will focus on eight of the 17 items of the interview that assess participant's understanding of *risk, benefits* and *voluntary participation.*

Data Analysis

All sources of data were uploaded to NVivo software for thematic data analysis. The coding process utilized thematic inductive approach as codes were created based on prevalent themes and patterns of meaning that emerged in the transcripts. Initial analysis included familiarization and review of the transcripts. Codes were then identified from adolescents' and parents' responses to items related to (risk, benefit and voluntariness) and assigned to the data to describe the content, followed by generation of themes and patterns. The last step in the analysis process included identifying the frequency of repetition in responses to questions and organizing similar responses into main themes. To achieve the aim of the preliminary analysis, themes from adolescents and parents were analyzed separately. Finally, coding results and theme identification were discussed with the Columbia University bioethics research team to maximize intercoder reliability.

Results

Fourteen in-depth interviews, from early (10-14-year-olds) (n= 5), mid (15-16-year-olds) (n=2), and parents/guardians (n=7), were qualitatively analyzed. The gender breakdown for the participants are: (n=4) adolescent participants and (n=3) adult participants identified as male; whereas (n=3) adolescents and (n=4) adults identified as female. This report sought to explore the capacity of adolescents in making independent decisions by testing their understanding of

various elements of informed consent. Adolescent responses were then compared with parents/guardians' responses; similarities and differences between the two groups are identified and discussed below. All 14 participants (7 adolescents, 7 parents/guardians) were included in the analysis process.

Understanding of Research Risks

Theme 1: Fear of Loss of Confidentiality

Both adolescents' and adults' response to questions pertaining to confidentiality or discomfort with sensitive topics showed their complete understanding of the concept confidentiality. Many adolescents described the possibility of sensitive data - such as HIV results or answers to private questions - being lost or mistakenly shared with other people. Some adolescents further elaborated upon the kinds of social problems they might encounter if their information became known by other people in their community. According to one adolescent participant:

> *If you tested me and discovered that I have HIV and then you tell that to someone else that person might start talking about me around the village, they might start isolating me in the village* (12 years, female).

This and similar responses indicate a broad understanding of the concept confidentiality and its consequences on their personal day-to-day lives on the parts of adolescents. Parents' response to loss of confidentiality questions differ slightly than those of adolescents. In addition to describing the concept confidentiality and how it may affect them, most adults explained that they are not concerned about their information being leaked; because they trust healthcare providers at RCCS will keep their personal information confidential. Which indicates a higher level understanding of disclosure protocols. One adult participant however discussed his fear of

loss of confidentiality because health providers who administer the blood tests are also from the same community.

> *Some of these researchers are born in our communities so we know their professions….you fear about a researcher born in your community to talk about you that even that one is living with HIV. It would be better to be worked on by researchers who don't know our personal background* (45 year old, male).

The comment from this parent participant displays his increased fear of loss of sensitive health data because of the health worker residing in same community. This response indicates that the participant may feel more comfortable discussing his health status with a health provider from a different community or someone who has less familiarity with the community they are collecting data from.

Theme 2: Fear of Domestic Violence

Three female parent participants mentioned domestic violence as a potential risk of participating in research that can occur as a result of loss of sensitive health information. These female Participants further explained their concern if their HIV results differ from husband's, that it can lead to violence at home.

> *P: A man cannot notice that his spouse discussed this matter with the service providers. So, it is likely to cause trouble or domestic violence in case a man gets rumors on what you did".*
> *I: How does this cause domestic violence?*
> *P: A man may assume that he is free from HIV. He would also start thinking that probably his partner started having sex with other sexual partners, and thus spread HIV. This may not be true because you may have got married and lived in a discordant couple relationship without your notice. It could have been true that one of you was not yet infected with HIV….Sometimes it may result into fighting each other, and separation in marriage* (40 year old, female).

A response from this respondent indicates the likelihood of facing domestic violence, if her husband learns about her HIV status from other people. While this finding was not mentioned by the interviewers as a part of the disclosure protocol pertaining to risks, respondents answer display their understanding of risks of loss of confidentiality.

Theme 3: Pain, Bleeding and Infection during Blood Draw

Almost all adolescent and adult participants mentioned at least two of the risks of a blood draw- e.g. pain, bleeding, bruising or discomfort- as described in the disclosure as probable participation risks. Some adolescents were cognizant of a risk of infection at injection site as a result of excessive bleeding, while others recognized an undisclosed risk – the possibility of contracting HIV by coming into contact with other infected individuals. However, no adolescents mentioned these risks as potential barriers to participating in future studies. With the exception of one adult participants, all other adults successfully listed risks associated with blood draw and described those risks as low. Adult participants additionally showed comparative reasoning capacity by describing how these minimal risks do not outweigh the benefits gained from participating in the study.

Research Benefits

Theme 1: Gaining access to HIV services

All adolescent participants listed at least one or more HIV services they can receive by participating in the research when asked about how people who enroll in RCCS directly benefit. The services they mentioned include HIV and other STDs testing/counseling, referrals for HIV care if positive, access to HIV treatments, and access to condoms. Many emphasized the

importance of knowing their HIV status and accessing free medical care as key benefits to participating in study. Most adult participants similarly highlighted accessing HIV services, testing and treatment as one of the fundamental benefits that motivate them to partake in the research project.

Theme 2: Reducing Risky Sexual Behavior

Some parents mentioned reducing risky sexual behaviors among young people as one of the benefits to be gained from HIV counselling services. They explained, by participating in research, young people receive counselling services which would help them change their risky sexual behaviors. As one participant said:

> *I also think that it brings about awareness to the community more especially those who are used to being promiscuous. A person who has been sensitized cannot be compared to someone who is not sensitized….RCCS helps these young people to protect themselves to avoid being promiscuous* (40 year old, female).

The parents' response indicate, some parents believe the HIV counselling services are one way of disciplining their children from engaging in "promiscuous sexual behavior" rather than a health education for themselves. Another respondent explained the challenge she faces in giving sexual health advise to her young child. She further expressed her appreciation of health workers at Rakai delivering sexual health information that prevents adolescents from being exposed to different sexually transmitted illnesses.

Theme 3: Receiving Compensation

Although interviewers did not discuss monetary compensation in the benefit disclosure, a few adolescent participants mentioned money as one of the study benefits. It is possible that these participants may have gained this information from other individuals in their community, or from

previous studies with monetary compensation that they themselves were involved in and assumed this study provides similar benefits. A couple of the adults correspondingly mentioned monetary compensation as a key benefits to study participation and described it as one of the motivating factors to stay in the study.

> *There are some people who participate in the study without money to buy salt at home. So, if you compensate him/her with 10,000=, he/she can go to buy salt or a book for the child* (45 year old, male).

Despite their source of information, this shows that both adolescent and adult participants have decision making skills and can apply the principles of logical reasoning.

Theme 4: Providing Benefit to the Rakai Community

Both adolescent and parent participants displayed knowledge towards community wide benefits gained from the project when asked about what benefits RCCS bring to the community. One adolescent stated how disease spread will reduce in the community as a result of the Rakai project and made the following comment:

> *People will benefit through receiving health education, and they will also know how they can use condoms. Another thing, people infected with TB in the community will receive TB treatment and the people with that disease will reduce* (14 years old, female).

Another adolescent participant listed knowing HIV status, accessing treatment, and geographical allocation of disease transmission to guide health care providers as benefits to the community.

> *It helps those who give health care services to know the health problems of people in that community. So that if they are to give health services, they will start with people in that community* (12-Year-old female).

A few of the adolescent respondents gave vague answers such as "to help people" and did not elaborate on their responses. However, their responses still show their partial cognition of the research project and its benefits to the community beyond individual benefit. Most adult participants also mentioned community benefits to be gained from RCCS study participation. Some of the benefits they listed included: access to medical care to the community, access to HIV testing, and prevention, and HIV counseling. One respondent mentioned mobile clinics (RCCS) bringing an extra source of income to the community during their seasonal visits because researcher buy food and drinks from local shops.

Voluntary Participation

Theme 1: Voluntariness

All adolescents and parents expressed complete understanding of the principle of voluntary participation. They clearly stated that they were not forced by researchers or other individuals to participate, rather they are taking part because they want to receive some of the benefits RCCS offers for active participants. The response from one adolescent participant reads:

> *You are free NOT to participate in research if you don't like it….participants can refuse to give blood (14 year old, Male).*

Theme 2 Inability to Withdraw

Many adolescent and adult participants displayed awareness about their ability to withdraw from the study anytime and that they can continue to receive medical care if they wish regardless of their decision to participate. However, few participants, both adolescents and adults, believed while study participants are generally allowed and free to leave at any time, they themselves cannot decline to participate.

Interviewer: "Are participants generally able to withdraw from, or leave the study"?
Participant : "Yes"
Interviewer: "What about you, are you able to withdraw from the study anytime"?
Participant : "For me I cannot withdraw anytime because I want to know my results. So, when I withdraw, I will not be able to know my HIV status" (16 year old, male).

Responses from the one mentioned above and others participants suggest, some participants believe that withdrawing from the research will change their ordinary access to care and adversely affect them.

Discussion

Overall, adolescents in this study demonstrated a large level of competence in relation to the ability to provide informed consent. Their conception of risk (how participating in the research would affect them personally and their day-to- day lives); the study's individual and community-wide benefit to Rakai community; and the concept of voluntary participation, were all well-understood by the majority of the adolescent participants.

Consistent with prior studies, the findings from this study analysis suggest that adolescents are capable of understanding concrete research procedures very well. There was not a noticeable difference between the responses of younger adolescents (age 10-14) and older adolescents (age 15-17) regarding the level of understandings of the elements of informed consent. A number of other studies also supported this claim. A study conducted in the Netherlands and Canada reported that competence to consent to research can be present in all adolescents including adolescents in the early age group (age10-14) (Hein et al., 2014; Schachter et al., 2005). Another study from the United States that assessed 14-21 year old adolescents' competence to consent to medical research reported that there is a positive correlation between age and health literacy and the capacity to consent (Nelson et al., 2016). A review article by

Kuther and Posada, that examined developmental literatures on children and adolescents' (age 6-18) capacities to make informed decisions, also supported this argument. As the authors stated, " adolescent and children have the potential to understand more about research procedure than recognized but the ability to fully comprehend research procedures and processes may not develop until late in childhood or early adolescence is reached" (Kuther & Posad'a, 2004, P. 166).

In comparing adolescent responses to those of adults, there was no significant difference in their level of understanding of the contents of the disclosures. In the section that assesses *loss of confidentiality*, most adult participants displayed a higher level of competence by describing potential risk of loss of personal data as well as their reasoning, how possibility of loss of data would not influence their decision to participate. In contrast, the adolescents only explained the possibility of loss of confidentiality and how it could affect them socially. Yet, adolescents' response also met the minimum expected response that verify their understanding of the research protocol.

Responses related to voluntariness showed both adolescents and adults understood that study participation is voluntary. This finding align with a previous research that assessed adolescent capacity in Netherlands, by McGregor and Ott. The researchers reported that all adolescent participants (with a mean age of 17 +/-3 years) in their study felt that they were capable of making a voluntary choice for themselves without requiring their parents or other adult permission. While evaluating the ability to withdraw, compared to adolescents, more parents/guardians believed that they themselves were unable to withdraw from the study because doing so would limit their access to medical care and other participatory benefits of the study.

These responses indicate a lack of understanding of the disclosure section on the parts of adults which states “Whether or not you agree to participate in the RCCS, you will have access to a number of services provided by the RHSP…”. Moreover, some adolescents displayed an even higher level of comprehension capability when compared to some adults regarding questions related to ability to withdraw anytime from the study.

A few female parent/guardian participants mentioned domestic violence as one of the risks to participating in HIV research as a consequence to loss of confidentiality. Prior research in sub-Saharan Africa also examined domestic violence as a result of loss of confidentiality or HIV status disclosure; and reported that individuals, mainly HIV positive women, experience violent physical and emotional reactions from their partners if they disclose their HIV status or if their partners learned about their HIV test results from elsewhere (Bott & Obermeyer, 2013; Iliyasu et al., 2011; Meskele et al., 2019). This finding suggests that domestic violence is a concern among female participants in HIV research as a result to loss of confidentiality. Future consent disclosures and study procedure should recognize and reinforce that they would minimize this risk of loss of confidentiality by keeping all information and results safe and protected - to the full extent allowed by law.

Limitations

This study has a few limitations that are worth noting. First, this version of MacCAT tool was modified and adapted for quantitative analysis with specific predetermined scores to indicate understanding of elements of the study. Due to the small number of data that are currently available for analysis, I was unable to complete quantitative analysis. However, the tool allowed interviewers to clarify complex questions in areas participants needed further

explanation through probing method. Second, the study is subjected to selection bias. Given participating adolescents (15-17 years old) and their parents were recruited from those who are enrolled in the annual RCCS cohort study, it is possible that some of the participants may already have a background knowledge about study procedures and the consent process. This limits the generalizability of the research findings to the general population with low health literacy and/or background knowledge about research participation process.

Conclusion

The findings from this study suggest that adolescents' knowledge and understanding of different elements of informed consent, i.e., risks, benefits, and voluntary participation, is similar to parents'/guardians' understanding. Adolescents also showed independent decision-making abilities demonstrating their capacity to self-consent in research. While it is important to protect vulnerable adolescents from harm, it is also essential to recognize adolescents' emerging capacity and their increased autonomy, especially while conducting research on sensitive topics such as HIV research. In those cases, it is critical to understand the social processes that influence young people's vulnerability that expose them to HIV infections. Parental consent requirements often limit critical information to be gained from adolescents, such as high-risk sexual behaviors.

Current international research ethics and international guidelines emphasize the importance of respecting the developing autonomy of adolescents. However, their participation is still hindered by legal and ethical issues. This paper reported a perspective in adolescent competency in understanding the contents of informed consent, therefore their ability to self-

consent. The findings from this study will contribute to shaping future research and policy guidelines regarding adolescent participation in research.

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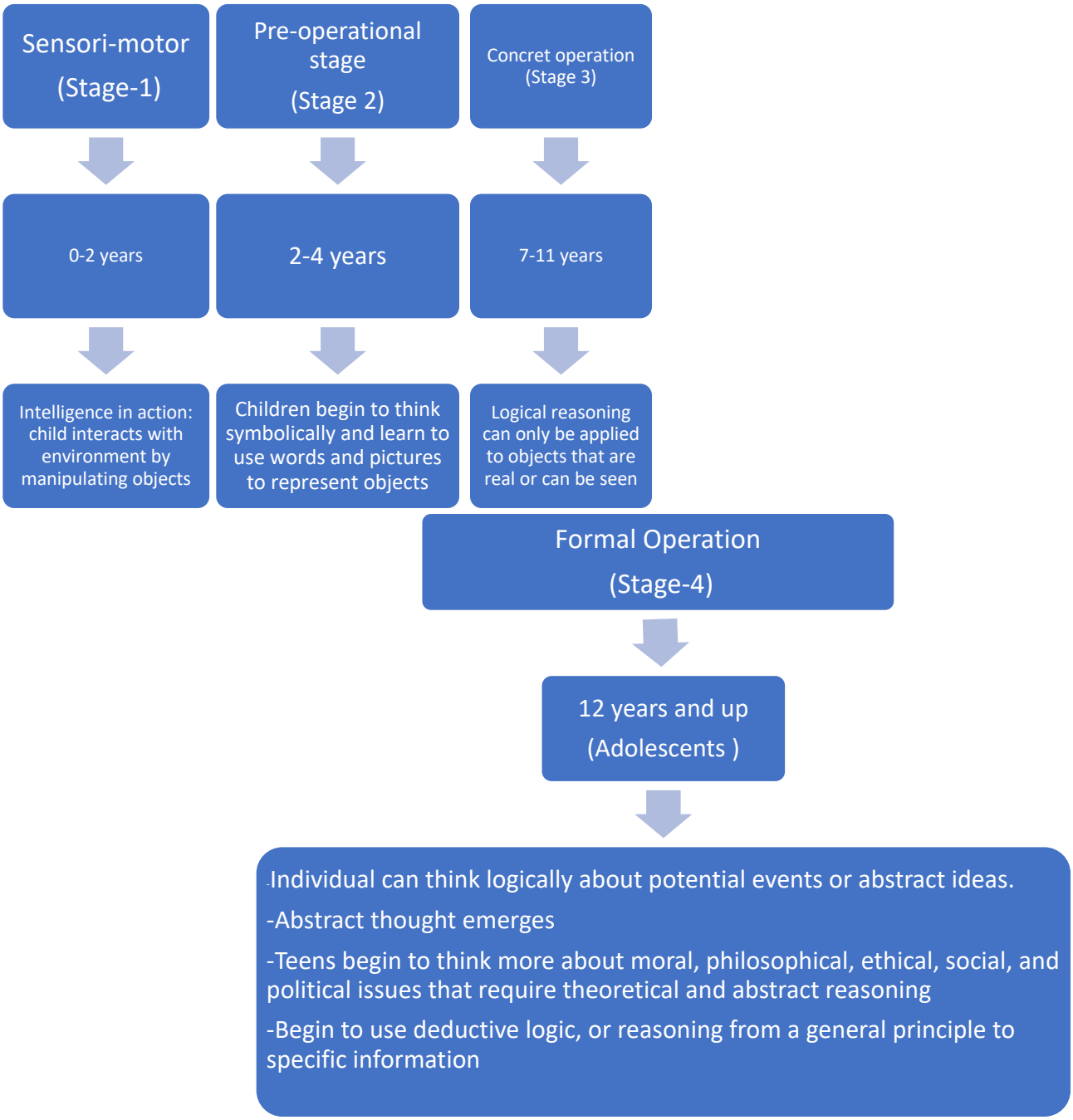
Appendix 1

Piaget's theory, child development stages.



Appendix 2

SSTAR Bioethics - MacArthur Competency Assessment Tool-Clinical Research Scoring Sheet

Questions	Interviewer Notes / Observations
DISCLOSURE – Understanding – Purpose and Procedures. You are being asked to join the Rakai Community Cohort Study (RCCS), a research study conducted by the Rakai Health Sciences Program (RHSP). The purpose of the RCCS is to learn more about health issues such as HIV and other infections, reproductive health, and non-infectious conditions in communities such as yours. If you consent to participate in the RCCS, you will be asked to let us take a photo for study identification, provide a blood specimen to test for HIV, and will be given an interview. During the interview, you will be asked questions about yourself, such as your age, marital status, sexual behaviors, and health. The interview and sample collection will take about 1 hour. If you test positive for HIV, you will be referred for free treatment. This is an ongoing study, and we will contact you every year for an interview and blood specimen. This consent form will also ask if you are willing to allow your blood or other biospecimens to be stored for additional research and if you agree to be contacted for future RHSP studies. The information we learn from your participation in the RCCS may help us to develop interventions to reduce HIV and improve health in your community. Do you have any questions? In your own words, what is your understanding of what I just said?	
DISCLOSURE - Understanding - Risks: Potential risks include: • Some bruising or bleeding at the site of the blood collection. There is also a very low risk of infections. RHSP provides training to its personnel to reduce the possibility of such risks**.** • You may get embarrassed, tired, or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer. • If the answers you provide during the interview or your HIV test results or other results became known, it might cause you social problems. We will minimize this risk by keeping all information and results safe and confidential, to the full extent allowed by law. Do you have any questions? In your own words, what is your understanding of what I just said?	
1. What are some risks about potentially participating in this study? a. If does not mention confidentiality, ask, " What will happen to your personal information?" **Kiki ekiyinza okutuuka**	**U6: Risk – Loss Confidentiality or discomfort with sensitive topics** 0= Does not mention loss of confidentiality with survey or HIV test, nor mention discomfort or sensitive topics 1= Vague answer, cannot provide adequate detail 2= Mentions potential loss of confidentiality and/or discomfort with sensitive topics

ku bikukwatako? and, if needed, "Do you have any concerns about confidentiality or sharing personal information?"**?** b. *If does not mention discomfort about sensitive topics, ask*, "Do you have any concerns about the topics to be discussed?"**?** c. If does not mention blood draw/needles, ask "Are there any physical risks or uncomfortable medical procedures?" Please explain?	**U7: Risk – Blood draw** 0= Does not mention blood draw 1= vague, uncertain, says blood draw but not why 2= Mentions bruising, bleeding, pain or discomfort, or mentions needles, fear of needles, or not liking needles or blood draw.

DISCLOSURE – Understanding – Benefits. Now we are going to discuss potential **benefits** or others might get from the research**:** Whether or not you agree to participate in the RCCS, you will have access to a number of services provided by the RHSP in collaboration with the District Health Office, such as health education, safe male circumcision, free or low cost condoms and referral to free Tuberculosis and HIV care and treatment for those who need it. The following additional benefits are available to RCCS participants:

- Individuals who provide a sample for testing can get their HIV results and counseling (if you are interested), and if they are HIV-infected they will be referred for free HIV treatment and services such as partner notification.
-
- The RHSP also offers free counseling and testing for couples in the RCCS.
  RHSP
  RCCS participants and their children will have access to free general health care provided by the RHSP mobile clinic available on some days during the RCCS survey.

- For women who are not sure whether or not they are pregnant, pregnancy may be confirmed by a urine test. All pregnant women will be offered a test for syphilis, and if they are infected, they will be provided with free treatment and if necessary, a referral for additional health services.

Do you have any questions?
Olinayo ekibuuzo kyonna?

In your own words, what is your understanding of what I just said?
Mu bigambo byo, kiki kyotegedde mu byenakamala okwogera?

2. Will the young people who enroll in RCCS directly benefit? If so, how will they benefit? If not, why not? a. You have told me XXX. What other benefits do you see for young people who	**U8: Lists individual benefits (HIV testing...)** 0= Does not mention potential individual benefits 1= general "help me be healthier" or similarly vague answer 2= Mentions one or more of the following: Individual gets tested/counseling for HIV and other STDs, referrals for HIV care if positive, medical care, compensation (money), testing for pregnancy, referral for circumcision

enroll in RCCS? (can rpeat if needed) b. If does not list HIV testing/ counseling/ treatment, free general health care, or pregnancy test, ask "Tell mo more benefits for young people who participating in this project?" **"**	
3. Will this project help your community? If so, how? a. What benefits does RCCS bring to the everyone in the Rakai community regardless of whether or not they participate in RCCS? **b.** You have told me XXX. What other benefits do you see for the Rakai community? (can repeat if needed)	**U9: Lists Community benefit** 0= Does not mention any community benefit 1= vague – "to help people" 2= Mentions one or more of the following: general medical care, access to HIV testing and prevention, or other community-wide benefit.
4. If does not list benefit to society or helping other youth, ask "Will this study help all young people? If so, how?" **"kutya?"**	(not scored, but will be qualitatively coded) Examples of societal benefit include learning more about adolescent HIV or adolescent/community health, or preventing HIV, opportunity to contribute.
DISCLOSURE - Voluntariness: Participation in the RCCS is voluntary. A participant is free to leave the study at any time and a person can decline to participate in any part of the study (e.g. interview, sample collection). Do you have any questions? In your own words, what is your understanding of what I just said?	
5. Are participants generally able to withdraw from, or leave, the study? **?**	**U10: Understands that an individual participant can withdraw at any time** 0= Believes participants are not allowed to withdraw once they start the study 1= unsure, vague 2= Knows participants can withdraw at any time
6. What about you personally? Are you able to withdraw from the study? a. Would you personally experience any consequences from the study b. If answer is Yes: Will leaving the study make it	**A1: Feel they personally can withdraw:** 0= Believes they personally cannot withdraw 1= vague answer, unsure of answer -or- has plausible reason for why withdrawing will adversely affect them individually 2= Understands that they can choose not to participate or to withdraw with no change in their ordinary access to care.

difficult for you to obtain health care in the future?" "If so, why?"	
7. **For any RCCS participant (usually 15 and older)::** Did you want to participate in the RCCS? Why or why not? Whose decision was it to participate in the RCCS? (Probes: your decision, your parents' or spouse's decision, both of your decisions?) **For 10-14 years 9not in RCCS):** Do you want to participate in the RCCS? Why or why not? a. Whose decision would it be to participate in the RCCS? (Probes: your decision, your parents' decision, both of your decisions?)	**C1: Able to express a choice** (Score together with question 17 below) = Does not state a choice to participate or not participate, says it is someone else's decision 1= Uncertain, state more than one choice 2= Clearly states a choice
18. A few moments ago you told me that you were/were not likely to want to participate in the research project. Now that we have discussed everything, what do you think about participating?	**C1: Able to express a choice** (coded with #13) 0= Does not state a choice to participate or not participate 1= Uncertain, state more than one choice, waivers 2= Clearly states a choice